

**IN THE CIRCUIT COURT OF THE THIRTEENTH JUDICIAL CIRCUIT  
IN AND FOR HILLSBOROUGH COUNTY, STATE OF FLORIDA**

JULIA W. ROSE,

Plaintiff,

Case No.: \_\_\_\_\_

Division: \_\_\_\_\_ 07-11595

**DIVISION F**

vs.

PFIZER INC., PHARMACIA CORPORATION,  
a wholly-owned subsidiary of PFIZER INC., and  
PHARMACIA & UPJOHN COMPANY, LLC, a  
wholly-owned subsidiary of PHARMACIA  
CORPORATION,

Defendant.

**COMPLAINT**

Plaintiff, JULIA W. ROSE, sues Defendants, PFIZER INC., PHARMACIA CORPORATION, a wholly-owned subsidiary of PFIZER INC., and PHARMACIA & UPJOHN COMPANY, LLC, a wholly-owned subsidiary of PHARMACIA CORPORATION, and alleges as follows:

**GENERAL ALLEGATIONS**

1. This is an action for damages in excess of \$15,000.00.
2. Plaintiff, JULIA W. ROSE, at all times material hereto, was a resident of Hillsborough County, Florida.
3. On December 23, 2004, Plaintiff JULIA W. ROSE, suffered a heart attack resulting in permanent damages and disability as a result of her ingestion of Bextra.
4. PFIZER INC. (hereafter referred to as "PFIZER") is a Delaware Corporation with its principal place of business at 235 E. 42nd Street, New York, NY.

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5. At all times material hereto, PFIZER was authorized and did conduct business within the State of Florida.

6. PHARMACIA CORPORATION ("PHARMACIA") is a Delaware Corporation with its principal place of business in New Jersey.

7. At all times material hereto, PHARMACIA was a wholly-owned subsidiary of PFIZER.

8. PHARMACIA & UPJOHN COMPANY, LLC ("PHARMACIA & UPJOHN") is a Delaware Corporation with its principal place of business in New York.

9. At all times material hereto, PHARMACIA & UPJOHN, was a wholly-owned subsidiary of Defendant PHARMACIA.

10. At all times material hereto, PFIZER was responsible for the liabilities of PHARMACIA and PHARMACIA & UPJOHN.

11. As used herein, Defendants PFIZER, PHARMACIA, and PHARMACIA & UPJOHN are collectively referred to as "BEXTRA DEFENDANTS".

12. At all times material, the BEXTRA DEFENDANTS were in the business of developing, manufacturing, selling, distributing, labeling, marketing and/or promoting Bextra for consumer use by prescription. The BEXTRA DEFENDANTS did develop, manufacture, design, package, market, sell and distribute Bextra in the State of Florida at all times relevant to this action.

13. This action arises out of the BEXTRA DEFENDANTS' manufacturing, selling, distributing, marketing and/or otherwise promoting Bextra in the State of Florida without proper warnings as to the dangers associated with its use.

14. The pharmaceutical drug Bextra, manufactured by the BEXTRA DEFENDANTS, is defective, dangerous to human health, and unfit and unsuitable to be marketed and sold in commerce.

15. Bextra (generic name valdecoxib) is a Cox-2 selective non-steroidal anti-inflammatory drug (NSAID).

16. Bextra is used in the treatment of arthritis and is among the class of drugs known as NSAIDs, which are non-steroidal anti-inflammatory drugs including aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil).

17. NSAIDs reduce pain and inflammation by blocking the body's production of pain transmission enzymes called cyclooxygenase (Cox-1 and Cox-2). Cox enzymes trigger the sequential oxidation of various fatty acids to create prostaglandins. Prostaglandins are important cogs in the physiology of pain, igniting hormone-like actions in the immediate vicinity of the cells that release them, thereby inducing inflammation, pain, and fever.

18. Because Cox enzymes and prostaglandins increase the pain associated with tissue injury, the synthesis of prostaglandins by cells of injured tissue becomes a reasonable target for pain-management drugs.

19. At the time the BEXTRA DEFENDANTS developed and manufactured Bextra, the BEXTRA DEFENDANTS intended to capture a portion of the extremely lucrative consumer market for Cox-2 specific inhibitors.

20. Bextra was approved on November 19, 2001, for marketing in the United States. Bextra was a second-generation Cox-2 inhibitor from PFIZER, which also manufactures Celebrex (celecoxib). Bextra, a stronger Cox-2 inhibitor than Celebrex, was approved for use in

patients with osteoarthritis and adult rheumatoid arthritis. Bextra is a selective Cox-2 inhibitor with similar selectiveness to Vioxx, a drug manufactured by Merck.

21. The scientific data available during and after Bextra's approval should have alerted the BEXTRA DEFENDANTS that its formulation of Bextra could cause a higher risk of clotting, stroke and/or myocardial infarctions among Bextra users. In addition, the scientific data available should have also alerted the BEXTRA DEFENDANTS that Bextra users faced special risks of potentially fatal skin and systemic reactions that were unique to Bextra.

22. Based upon the scientific data available in its own studies, the BEXTRA DEFENDANTS knew or in the exercise of reasonable care should have known that additional testing should be performed to determine the adverse health effects of Bextra on intended consumers.

23. In approximately June of 2003, the BEXTRA DEFENDANTS completed a study that showed an excess risk of cardiovascular events for persons ingesting Bextra. As reported in the Wall Street Journal, "*PFIZER to Begin Test of Celebrex as Heart Attack Inhibitor; Questions Raised on Timing, C-5*," the BEXTRA DEFENDANTS had possession of the adverse cardiovascular data from a second study at least by August of 2004, but failed to make any disclosure until after October 15, 2004. The BEXTRA DEFENDANTS referred to the adverse cardiovascular thrombotic events at issue as an "open question" since the studies were on non-indicated uses, and the BEXTRA DEFENDANTS had not done the necessary long-term, prospective, randomized placebo controlled clinical trials to further quantify the risk.

24. The BEXTRA DEFENDANTS were also aware of a study published by Dr. Eric Topol in August of 2001 in the *Journal of the American Medical Association* that reported an increased risk of thrombotic cardiovascular events in persons who used Cox-2 inhibitors. The

study theorized that Cox-2 inhibitors interfered with platelet aggregation and had the potential to cause clot formation. Dr. Garrett Fitzgerald, of the University of Pennsylvania, in an editorial published in the *New England Journal of Medicine* on October 21, 2004, reported that it was known as early as 1999 that the Cox-2 inhibitors suppressed the formation of prostaglandin I<sub>2</sub> in healthy volunteers, that this action inhibited platelet aggregation *in vitro*, and that this may predispose patients to myocardial infarction or thrombotic stroke.

25. Based upon available scientific data, the BEXTRA DEFENDANTS knew or should have known that the study group involved in its own testing did not adequately represent the cross-section of individuals who were the intended consumers likely to take Bextra. Therefore, the testing performed was inadequate.

26. At all times up until Plaintiff was injured, the BEXTRA DEFENDANTS did not carry out research specifically to determine whether their product could cause the injury Plaintiff sustained, nor at what incidence it occurred, nor in what populations of foreseeable users this product created an increased risk.

27. Had the BEXTRA DEFENDANTS conducted adequate testing prior to launching Bextra, the scientific data would have revealed significant increases in the risk of stroke and heart attacks amongst the intended population of Bextra consumers.

28. In fact, post-marketing data has revealed increased risks of clotting, stroke and myocardial infarction, but that information was intentionally suppressed by the BEXTRA DEFENDANTS in order for the BEXTRA DEFENDANTS to gain significant profits from Bextra sales.

29. At all times up until the Plaintiff was injured, the BEXTRA DEFENDANTS were aware that their product could cause serious skin reactions including Stevens Johnson Syndrome,

Toxic Epidermal Necrolysis (TENS), and Erythema Multiforme, and did not adequately inform the Food and Drug Administration, the medical profession, the physician who prescribed the drug, Plaintiff, the pharmacy where the prescription was filled, or the consuming public that Bextra could cause these life threatening injuries.

30. At all times up until Plaintiff was injured, the BEXTRA DEFENDANTS did not include any contradictions in its labeling as to certain types of persons who would be at higher risk in using Bextra, including those risk factors which Plaintiff had during the time that she ingested Bextra.

31. At all times up until Plaintiff was injured, the BEXTRA DEFENDANTS were aware of but concealed from Plaintiff, the Food and Drug Administration, the medical profession, the physician who prescribed the drug, the pharmacy where the prescription was filled, and the consuming public that Bextra could cause serious skin reactions including Stevens Johnson Syndrome, Toxic Epidermal Necrolysis (TENS), and Erythema Multiforme and that there were certain users who were at an increased risk of having that injury occur.

32. The BEXTRA DEFENDANTS' failure to conduct adequate testing and/or additional testing prior to its market launch was based upon the BEXTRA DEFENDANTS' desire to generate maximum financial gains for itself and to gain a significant market share in the highly competitive Cox-2 inhibitor market.

33. At the time that the BEXTRA DEFENDANTS manufactured, advertised, and distributed Bextra to consumers, the BEXTRA DEFENDANTS intentionally ignored and/or withheld information regarding the increased risks of life threatening skin and systemic reactions, hypertension, stroke and/or myocardial infarctions because the BEXTRA

DEFENDANTS knew that if such increased risks were disclosed, consumers would not purchase Bextra.

34. At all times relevant hereto, the BEXTRA DEFENDANTS engaged in a marketing campaign with the intent that consumers would perceive Bextra as a safer and more efficacious drug than its competitors and, thereby, purchase Bextra.

35. The BEXTRA DEFENDANTS widely and successfully marketed Bextra throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of Bextra in order to induce widespread use and consumption. Bextra was represented to relieve the pain and discomfort of arthritis, osteoarthritis, and related problems. The BEXTRA DEFENDANTS made misrepresentations through product inserts, advertising, detailing, promotional materials, and other aggressive marketing efforts.

36. The BEXTRA DEFENDANTS failed to perform adequate testing. Adequate testing would have shown that Bextra possessed serious side effects. The BEXTRA DEFENDANTS should have taken appropriate measures to ensure that its defectively designed product would not be placed into the stream of commerce and/or should have provided full and proper warnings that accurately and fully reflected the scope and severity of those side effects.

37. Prior to the manufacturing, sale, and distribution of Bextra, the BEXTRA DEFENDANTS, through its officers, directors, and managing agents, had notice and knowledge from several sources that Bextra presented substantial and unreasonable risks of harm to the consumer. As such, Bextra consumers, including Plaintiff, were unreasonably subjected to risk of injury or death from the ingestion of Bextra.

38. In addition, the BEXTRA DEFENDANTS had notice from numerous sources that Cox-2 inhibitors as a whole might present unreasonable risks of harm to consumers based upon

various studies that had been published with regard to Vioxx and even its own Cox-2 inhibitor, Celebrex. Rather than heed these warnings, the BEXTRA DEFENDANTS instead chose to attempt to capitalize on negative news about Vioxx in hopes of selling more Bextra.

39. Despite such knowledge, the BEXTRA DEFENDANTS, through its officers, directors, and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Bextra, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in the formulation of Bextra. The BEXTRA DEFENDANTS and its officers, agents and managers intentionally proceeded with the manufacturing, sale, and marketing of Bextra, knowing that persons would be exposed to serious potential dangers in order to advance their own pecuniary interests.

40. At all times up until Plaintiff was injured, the BEXTRA DEFENDANTS were aware of but concealed from Plaintiff, the Food and Drug Administration, the medical profession, the physician who prescribed the drug, the pharmacy where the prescription was filled, and the consuming public that the pain for which Plaintiff ingested Bextra could be treated as effectively, more safely, and cheaply by over-the-counter NSAID drugs.

41. In January of 2005, the FDA issued a letter reprimanding the BEXTRA DEFENDANTS for their false and misleading marketing of its products, including Bextra. The letter advised the BEXTRA DEFENDANTS that its marketing schemes "omit material facts, including the indication and risk information; fail to make adequate provision for the dissemination of the FDA-approved product labeling; and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims" and "therefore [are] in violation of the Federal Food, Drug, and Cosmetic Act (Act) and FDA implementing



regulations." The FDA called upon the BEXTRA DEFENDANTS to "immediately cease the dissemination of promotional materials" for Bextra.

42. On April 7, 2005, Bextra was removed from the market. According to an FDA Public Health Advisory, Bextra was taken off the market for three reasons:

- a. increased risk of heart attack and stroke;
- b. increased risk of serious and life threatening skin reactions; and
- c. there was no advantage associated with Bextra when compared with other cheaper and safer NSAIDs.

43. The BEXTRA DEFENDANTS promoted the sale of Bextra by misleading users about the efficacy of the product and by failing to adequately warn users (including Plaintiff) and prescribing physicians of the serious dangers which the BEXTRA DEFENDANTS knew or should have known were associated with the use of Bextra, including an increased risk of adverse cardiovascular events and severe skin reactions.

44. The BEXTRA DEFENDANTS failed to perform adequate pre-marketing and post-marketing testing of Bextra and likewise failed to thoroughly and objectively analyze and/or report the data generated by the testing it conducted. In promoting Bextra to the medical community, the FDA, and the general public, the BEXTRA DEFENDANTS systematically minimized the risks suggested by clinical data while overstating the alleged efficacy and purported safety of Bextra. Adequate testing and objective reporting of those tests conducted would have demonstrated and revealed to the public and medical community the increased risk of cardiovascular events and severe skin reactions associated with the ingestion of Bextra.

45. At the time the BEXTRA DEFENDANTS manufactured, advertised, and distributed the BEXTRA DEFENDANTS to consumers including Plaintiff, the BEXTRA DEFENDANTS intentionally or recklessly ignored and/or withheld information regarding the

increased risks of serious skin reactions, hypertension, stroke and/or myocardial infarctions because the BEXTRA DEFENDANTS knew that if such increased risks were disclosed, consumers would not purchase Bextra, but instead would purchase other cheaper and safer NSAID drugs.

46. The BEXTRA DEFENDANTS misrepresented the safety and effectiveness of Bextra to prescribing physicians, Plaintiff, scientific journals, and the consuming public, and concealed or understated the dangerous side effects associated with ingestion of Bextra. The BEXTRA DEFENDANTS also engaged in such aggressive, improper, and dishonest promotion to certain physicians that the prescribing physicians were no longer able to make independent decisions as a learned intermediary on behalf of their patients.

47. The BEXTRA DEFENDANTS engaged in a pattern of reckless behavior and manipulation with regard to the promotion and sale of Bextra in a successful effort to enhance profits at the expense of the public health.

48. As a direct result of the BEXTRA DEFENDANTS' misconduct, the Plaintiff was prescribed and ingested Bextra and suffered significant harm.

49. Plaintiff used Bextra as prescribed and in a foreseeable manner.

50. Plaintiff ingested Bextra that was in a condition substantially identical to the condition in which it was manufactured and sold.

51. Plaintiff would not have ingested Bextra had the BEXTRA DEFENDANTS properly disclosed the risks associated with the drug.

52. As a direct and proximate result of the defective condition of the Bextra manufactured and marketed by the BEXTRA DEFENDANTS and ingested by Plaintiff, Plaintiff has suffered and continues to suffer from serious injuries, including, but not limited to, pain and

suffering, physical injuries, disability, disfigurement, embarrassment, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical, nursing care and treatment, loss of earnings, loss of the ability to earn money in the future, and a shortened life span.

## **COUNT I**

### **STRICT LIABILITY**

Plaintiff adopts by reference all of the General Allegations contained in Paragraphs 1 through 52 above, each inclusive, as though fully set forth herein, pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

53. The Bextra ingested by Plaintiff was defective and unreasonably dangerous when it left the possession of the BEXTRA DEFENDANTS in that:

- a. When placed into the stream of commerce, Bextra contained unreasonably dangerous design defects and was not reasonably safe in the condition as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of the drug;
- b. When placed into the stream of commerce, Bextra was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Plaintiff's ailment;
- c. Bextra contained insufficient warnings to alert Plaintiff, consumers, and prescribing physicians of severe and life threatening complications and side effects including, but not limited to arterial thrombus and severe skin reactions;
- d. Their advertising and promotion concerning the benefits of using Bextra was misleading and false;
- e. There were inadequate post-marketing warnings or instructions for Bextra because, after the BEXTRA DEFENDANTS knew or should have known of the significant risks associated with the use of Bextra, the BEXTRA DEFENDANTS failed to provide adequate warnings to Plaintiff, consumers, and prescribing physicians, and continued to aggressively

promote and advertise Bextra to physicians and other health care providers and directly to consumers; and

- f. The Bextra ingested by Plaintiff had not been materially altered or modified prior to use.

54. Plaintiff used the drug for its intended purpose of pain management.

55. The BEXTRA DEFENDANTS, as manufacturers of a prescription drug, are held to the level of knowledge of an expert in the field.

56. Plaintiff's prescribing physician did not have substantially the same knowledge as the BEXTRA DEFENDANTS, or the amount of knowledge that would have been gleaned from an adequate warning from the BEXTRA DEFENDANTS.

57. The warnings that were given by the BEXTRA DEFENDANTS to prescribing physicians, consumers, and Plaintiff were inaccurate, unclear, and/or ambiguous.

58. The BEXTRA DEFENDANTS had a continuing duty to warn the Plaintiff, consumers and prescribing physicians of the dangerous risks and reactions associated with Bextra.

59. Plaintiff could not have discovered any defect in the product through the exercise of care.

60. As a direct and legal result of the defective condition of Bextra and inadequate warnings, Plaintiff suffered serious personal injury, has sustained economic losses, and has expended (and/or may in the future be required to expend) fair and reasonable expenses for necessary health care, attention and services, and has and/or may incur incidental and related expenses.

WHEREFORE, Plaintiff demands judgment against the BEXTRA DEFENDANTS for damages, as well as costs of this action and a trial by jury of all issues to be tried.

## COUNT II

### NEGLIGENCE

Plaintiff adopts by reference all the General Allegations contained in Paragraphs 1 through 52 above, each inclusive, as though fully set forth, pursuant to Rule 1.130 (b), Florida Rules of Civil Procedure.

61. At all times material hereto, the BEXTRA DEFENDANTS had a duty to Plaintiff to exercise reasonable care in the design, manufacture, testing, processing, promotion, advertising, marketing, labeling, assembling, packaging, distribution and sale of Bextra.

62. The BEXTRA DEFENDANTS were negligent in its actions, misrepresentations, and omissions toward Plaintiff and Plaintiff's prescribing physician in the following ways:

- a. They failed to include adequate warnings with the drug that would have alerted consumers and physicians to the potential risks and serious side effects of Bextra;
- b. Failed to adequately and properly test Bextra before placing the drug on the market;
- c. Failed to provide adequate post-marketing warnings or instructions after the BEXTRA DEFENDANTS knew of the significant risks of personal injury and death as identified herein associated with the use of Bextra;
- d. Failed to adequately warn Plaintiff that Bextra should not be used in conjunction with any risk factors for these adverse effects;
- e. Failed to adequately disclose and warn Plaintiff that Plaintiff undertook the risk of adverse events and death by ingesting Bextra; and
- f. Failed to adequately and timely inform the health care industry of the risks of serious personal injury and death from Bextra ingestion as described therein.

63. The BEXTRA DEFENDANTS knew or should have known that Bextra caused unreasonably dangerous risks and serious side effects of which Plaintiff, Plaintiff's prescribing physician, and the consuming public was unaware. The BEXTRA DEFENDANTS nevertheless

aggressively advertised, marketed, promoted sold and distributed Bextra knowing that there were safer methods and products for treatment of pain due to inflammation.

64. As a direct and legal result of the negligence of the BEXTRA DEFENDANTS, Plaintiff suffered serious injury, and Plaintiff seeks all damages allowed under the law.

WHEREFORE, Plaintiff demands judgment against the BEXTRA DEFENDANTS for damages, as well as costs of this action and a trial by jury of all issues to be tried.

### COUNT III

#### **NEGLIGENT MISREPRESENTATION**

Plaintiff adopts by reference all of the General Allegations contained Paragraphs 1 through 52 above, each inclusive, as though fully set forth, pursuant to Rule 1.130 (b), Florida Rules of Civil Procedure.

65. The BEXTRA DEFENDANTS negligently misrepresented to Plaintiff, Plaintiff's prescribing physician, and the consuming public the safety and effectiveness of Bextra and/or negligently misrepresented material information regarding Bextra and/or negligently misrepresented adverse information regarding the safety and effectiveness of Bextra.

66. The BEXTRA DEFENDANTS' negligent misrepresentations were communicated to Plaintiff and to Plaintiff's prescribing physician with the intent that they reach the Plaintiff, and that the effect of such representations would be that prescriptions would be written for Bextra for the consuming public, including Plaintiff.

67. The BEXTRA DEFENDANTS misrepresented safety information regarding Bextra with the intention and specific desire that Plaintiff, Plaintiff's prescribing physician or other dispensing entities, and the consuming public would rely on such information in selecting, requesting, or prescribing treatment.

68. The BEXTRA DEFENDANTS misrepresented material, adverse information regarding the safety and effectiveness of Bextra.

69. The BEXTRA DEFENDANTS made these misrepresentations and actively concealed adverse information at a time when the BEXTRA DEFENDANTS knew, or should have known, that Bextra had defects, serious side effects, dangers, and characteristics that were other than what the BEXTRA DEFENDANTS had represented to prescribing doctors or other dispensing entities, the FDA and the consuming public, including the Plaintiff herein.

70. The misrepresentations of the BEXTRA DEFENDANTS were perpetuated directly and/or indirectly by the BEXTRA DEFENDANTS' employees, agents and/or other detail persons.

71. The misrepresentations of the BEXTRA DEFENDANTS constitute a continuing tort.

72. Through the Bextra product inserts, promotional materials, manipulation of science and the media, and aggressive marketing, the BEXTRA DEFENDANTS continued to misrepresent the potential risks and benefits associated with Bextra both before and after Plaintiff's ingestion of the drug.

73. The BEXTRA DEFENDANTS had a post-sale duty to warn Plaintiff, the consuming public, and prescribing physicians about the potential risks and complications associated with Bextra in a timely manner.

74. The BEXTRA DEFENDANTS misrepresented the safety and efficacy of Bextra in their labeling, advertising, product inserts, promotional materials, or other marketing efforts.

75. Plaintiff, Plaintiff's prescribing physician, other dispensing entities, and the consuming public justifiably relied on and/or were induced by the misrepresentations of the BEXTRA DEFENDANTS to Plaintiff's detriment.

76. As a direct and legal result of the negligent misrepresentations of the BEXTRA DEFENDANTS, Plaintiff has suffered serious injuries.

WHEREFORE, Plaintiff demands judgment against the BEXTRA DEFENDANTS for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

#### **COUNT IV**

##### **FRAUD**

Plaintiff adopts by reference all of the General Allegations contained Paragraphs 1 through 52 above, each inclusive, as though fully set forth, pursuant to Rule 1.130 (b), Florida Rules of Civil Procedure.

77. The BEXTRA DEFENDANTS fraudulently or intentionally misrepresented to Plaintiff, Plaintiff's prescribing physician, and consumers the safety and effectiveness of Bextra and/or fraudulently or intentionally concealed material information regarding the drug and/or fraudulently or intentionally misrepresented adverse information regarding the safety and effectiveness of Bextra.

78. The BEXTRA DEFENDANTS' fraudulent or intentional misrepresentations were communicated to Plaintiff and to Plaintiff's prescribing physician with the intent that they reach the Plaintiff.

79. The BEXTRA DEFENDANTS knew that their representations were false.

80. The BEXTRA DEFENDANTS made the fraudulent or intentional misrepresentations and/or actively concealed information about the risks and efficacy of Bextra



with the intention and specific desire that the Plaintiff, the Plaintiff's prescribing physician, dispensing entities, and the consuming public would rely on such false information in selecting treatment for pain and inflammation.

81. The BEXTRA DEFENDANTS intentionally concealed material, adverse information regarding the safety and effectiveness of their products.

82. The BEXTRA DEFENDANTS made these fraudulent or intentional misrepresentations and actively concealed adverse information at a time when the BEXTRA DEFENDANTS knew that Bextra had defects, serious side effects, dangers, and characteristics that were other than what the BEXTRA DEFENDANTS had represented to the prescribing doctors or other dispensing entities, the FDA and the consuming public, including the Plaintiff herein. Specifically, the BEXTRA DEFENDANTS fraudulently or intentionally misrepresented to and/or actively concealed from Plaintiff, Plaintiff's prescribing physician or other dispensing entities, the FDA and the consuming public the following adverse information regarding the Bextra ingested by the Plaintiff:

- a. Failed to advise Plaintiff, Plaintiff's prescribing physician, and others that Bextra carried risks of serious adverse effects;
- b. Failed to advise Plaintiff, Plaintiff's prescribing physician, and others that there were serious risks of serious skin reactions and thrombotic events associated with Bextra, and, instead, the BEXTRA DEFENDANTS aggressively marketed, promoted, advertised directly to consumers, and/or sold Bextra as if there was no risk; and
- c. Failed to advise Plaintiff, Plaintiff's prescribing physician, and others that prior studies, research, reports and/or testing had been conducted linking Bextra to serious adverse reactions.

83. The fraudulent or intentional misrepresentations and/or active concealment by the BEXTRA DEFENDANTS were perpetuated directly and/or indirectly by the BEXTRA DEFENDANTS and their employees, agents and/or other detail persons.

84. The fraudulent or intentional misrepresentations and/or concealment by the BEXTRA DEFENDANTS constitute a continuing tort.

85. Through the BEXTRA DEFENDANTS' product insert, promotional materials, manipulation of science and the media, and aggressive marketing efforts, the BEXTRA DEFENDANTS continued to fraudulently or intentionally misrepresent the potential risks associated with Bextra.

86. The BEXTRA DEFENDANTS had a post-sale duty to warn Plaintiff, consumers, and prescribing physicians of the risks of Bextra in their labeling, advertising, product inserts, promotional materials, direct-to-consumer advertising, and other marketing efforts.

87. The BEXTRA DEFENDANTS fraudulently or intentionally misrepresented the safety and efficacy of Bextra in their labeling, advertising, product insert, promotional materials, direct-to-consumer advertising, or other marketing efforts.

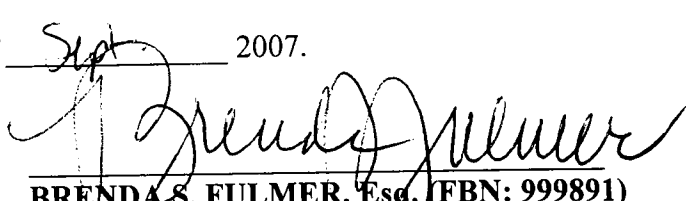
88. Plaintiff, Plaintiff's prescribing physician, other dispensing entities, and the consuming public justifiably relied on and/or were induced by the fraudulent or intentional misrepresentations and/or active concealment by the BEXTRA DEFENDANTS to Plaintiff's detriment.

89. As a direct and legal result of the fraudulent or intentional misrepresentations of and/or active concealment by the BEXTRA DEFENDANTS, Plaintiff suffered serious injuries.

WHEREFORE, Plaintiff demands judgment against the BEXTRA DEFENDANTS for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

**JURY TRIAL DEMANDED ON ALL ISSUES**

Dated this the 10<sup>th</sup> day of Sept 2007.



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